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08/948/24

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/948,124 10/09/97 REINHERZ

EXAMINER

HM21/0915

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ART UNIT	PAPER NUMBER
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1642
DATE MAILED:

09/15/98

This is a communication from the examiner in charge of your application.
*COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire - 0 - month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-52 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-52 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

☒ Other
Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Restriction Election *Facsimile Transmission*
-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, drawn to an isolated caspase molecule, classified in class 435, subclass 226.
 - II. Claims 9-25, drawn to isolated nucleic acid encoding caspase, vectors, host cells and method of using host cells to produce caspase, classified in class 536, subclass 23.5.
 - III. Claims 26-27, drawn to an antibody to caspase molecule, classified in class 530, subclass 395.
 - IV. Claims 28-29, drawn to method of assaying for caspase activity, classified in class 435, subclass 7.1.
 - V. Claims 30, 32, 34, drawn to a method of identifying an inhibitor of caspase, classified in class 435, subclass 7.1.
 - VI. Claims 31, 33, drawn to an inhibitor of caspase, classified in class 514, subclass 2.
 - VII. Claims 35-40, drawn to a method of inhibiting apoptosis, classified in class 435, subclass 7.1.
 - VIII. Claims 41, 43, 45, 46, drawn to a method of identifying for an enhancer of caspase, classified in class 435, subclass 7.1.
 - IX. Claims 42, 44, drawn to an enhancer of apoptosis, classified in class 514, subclass 2.
 - X. Claims 46-48, drawn to a method of enhancing apoptosis, classified in class 435, subclass 7.1.
 - XI. Claims 49-50, drawn to a method of treating autoimmune disease, classified in class 514, subclass 2.

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XII. Claims 51, drawn to a method of enhancing immune response, classified in class 514, subclass 2.

XIII. Claims 52, drawn to a method of treating cancer, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, VI and IX are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.E.P.. § 806.04, M.E.P.. § 808.01). In the instant case the different inventions are patentably distinct because of the following reasons:

A. Groups IV, V, VIII, are drawn to methods of assaying for caspase activity or agents that inhibit or enhance caspase activity, that are independent and different from methods of treatment as in Groups XI-XIII. Similarly, the methods of identifying agents for inhibiting or enhancing apoptosis as in Groups VII and X are independent and different from methods of Groups IV, V, VIII and XI-XIII. Each of these methods have different modes of operation, result in different endpoints and functions, and hence belong to patentably distinct groups. Groups IV, V and VIII are also independent and distinct from each other as their method steps are different. Groups XI-XIII are also independent and distinct from each other as their method steps and end points are different.

B. Groups I-III, VI, IX are drawn to products which are chemically and structurally and functionally different from each other. The products of Groups I and II are different from the invention of Group III which is drawn to antibody. The methods required for to isolate the products of Group III are different from the methods required for isolating the product of Groups I and II. The products from both groups I and II are structurally and functionally different from each other and are thus patentably distinct. The products of Groups VI and IX are similarly

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independent and distinct from the products of Groups I-III because of differences in structure and function.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and their recognized divergent subject matter, and because the search required for the different groups is different, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer

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service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

6. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 6:30am to 4:00pm and alternate Fridays from 6:30am to 3:00pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.
8. Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [lila.feisee@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Geetha P. Bansal

September 11, 1998.

Toni R. Scheiner

TONI R. SCHEINER
PRIMARY EXAMINER
GROUP 1600